

### **REMARKS**

Claims 1, 3-7, 20-21, 35-37, 39, 41, 43, 45, and 49 are pending. Claims 2, 8-19, 22-34, 38, 40, 42, 44, and 46-48 are currently cancelled. Claims 36-37, 39, 41, 43, and 45 have been withdrawn from consideration. Claims 1 and 35 are currently amended. Reconsideration of the application is requested.

### **Amendments**

Independent claims 1 and 35 have been amended, without prejudice, to include the limitation, “wherein the immune response modifier is N-{2-[4-amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide, or a pharmaceutically acceptable salt thereof.” This limitation is incorporated from original claim 19 and the compound is also set out as IRM1 in Table 1 and exemplified in Applicants’ specification at Example 132 with results shown in Figures 1 and 2.

### **§ 103 Rejections**

Claims 1-7, 15-21 and 35 and 49 stand rejected under 35 USC § 103(a) as being unpatentable over Hedenstrom et al. (US 6,706,728) (hereinafter, “Hedenstrom”) or Miller et al. (US 6,083,505) (hereinafter, “Miller”) in view of Gizurarson (US 6,647,980) (hereinafter, “Gizurarson”) and further in view of Kublik et al. (“Nasal delivery systems and their effect on deposition and absorption” in Advanced Drug Delivery Reviews, 29 (1998), pp 157-177) (hereinafter, “Kublik”).

The Office Action states that both Hedenstrom and Miller disclose compositions comprising the immune response modifier or pharmaceutically acceptable salts of the claims. However, it should be noted that the IRM1 compound N-{2-[4-amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide required by original claim 19, and now incorporated into claims 1 and 35, is not disclosed in Hedenstrom or Miller. Example 132 and Figures 1 and 2 of the application exemplify and show the beneficial results of claimed formulations using this IRM1 compound.

Neither Gizurarson nor Kublik remedy the deficiencies of Miller and Hedenstrom because neither reference discloses or suggests the presently claimed IRM1 compound. Also,

the Office Action provides insufficient explanation as to how one of skill in the art would have been motivated to modify the immune response modifier (IRM) compounds of Hedenstrom and Miller, which do not disclose the claimed IRM1 compound, to achieve the presently claimed composition containing this particular IRM compound with reasonable expectation of success.

Thus, independent claims 1 and 35, and dependent claims 3-7, 20-21, and 49 are patentable over Hedenstrom or Miller in view of Gizurarson and further in view of Kublik.<sup>1</sup>

In view of the above, it is submitted that the application is in condition for allowance.

Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

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<sup>1</sup> It should also be noted that, since original claim 19 was already limited to N-{2-[4-amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide, Applicants believe that any newly cited art or rejection regarding the subject matter of the presently amended claims would not have been necessitated by amendment.